**Interventional and Research Studies Serious Adverse Event Reporting Form**

(Barts Health NHS Trust/Queen Mary University of London

sponsored studies)

Please only send unexpected Serious Adverse Reactions to the JRMO

|  |  |
| --- | --- |
| Report type:  | Initial □ Follow up □  |
| **If the study is multi-site, the section below should be completed by the main site study coordinator prior to sending the template to the sites** |
| Full title of the study: |  |
| Name of sponsor: | Barts Health □ Queen Mary □  |
| IRAS number: |  |
| Chief Investigator: | Name: Phone No:Email address:  |
| **This section should be completed by the SITE:** |
| Principal Investigator: | Name: Email address: Phone No:  |
| Site number: | Site name: |
| Date of site becoming aware of the event  | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| Patient ID: | Patient Age: | Patient Gender: □ Male □ Female  |
| Event Description (e.g. body site, symptoms) (\*please use separate form for each event) | Event\*:   |
| Onset date of SAE: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) | Resolution date of SAE: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| Severity:  | Mild □ | Moderate □ | Severe □ |
| Type of SAE:  | Results in death  | □  |
| Life threatening  | □  |
| Hospitalisation or prolongation of hospitalisation  | □  |
| Persistent or significant disability or incapacity  | □  |
| Congenital anomaly or birth defect  | □  |
| “Other” important medical event  | □ If “Other”, please describe: |
| Is the SAE likely to be a reaction to one of the IMPs in the trial? a | Procedure 1 (specify)  | **□** Reasonably possible | **□** Not reasonably possible |
| Procedure 2 (specify)  | Reasonably possible | **□** Not reasonably possible |
| Is the SAE expected? | Procedure 1 (specify)  | **□ Expected**  | **□ Unexpected**  |
| Procedure 2 (specify)  | **□ Expected**  | **□ Unexpected**  |
| Is the SAE due to the progression of an underlying illness?  | Yes □ No □ |
| Action taken with study treatment and procedures:  | Continued □ Reduced □ Increased □Temporary stop □ Permanent stop □ |
| Did the PI withdraw the patient from the study? | Yes □ No □  |
| Outcome of SAE: | Resolved  | □  |
| Resolved with sequelae\*  | □  | \*specify sequelae |
| Improved  | □ |
| Persisting  | □ |
| Worsened  | □ |
| Fatal  | □ (Insert date of death \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) | If fatal, copy of post-mortem available? Yes □ No □  |
| Unknown  | □ |
| Person completing the form if not the PI | Name: Role: Email address: Signature: Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| PI signature |   Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |

**For CI use only – unexpected serious adverse reactions**

|  |  |
| --- | --- |
| CI assessment: | Date reported to the REC:  \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |